PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**John Eric Peckham**
Application No.:	**10/719421**
Filed:	**November 21, 2003**
For:	**Rotational Markers**
Examiner:	**Jacqueline Cheng**
Group Art Unit:	**3768**

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-11294-US01

APPEAL BRIEF

This is an Appeal Brief for the above-identified Application, in which claims 1-27, 36 and 37 were rejected in the Final Office Action mailed September 18, 2008. A Notice of Appeal was filed in this case on December 18, 2008. This brief is submitted in accordance with 37 CFR. § 41.37. The fees required under 37 CFR § 41.20, and any petition for an extension of time required for filing this brief, are addressed in the accompanying Transmittal Letter.

A Table of Contents is included on page 2 of this document.

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(i) Real Party in Interest

The Application is assigned to Boston Scientific Scimed, Inc. (formerly Scimed Life Systems, Inc.), One Scimed Place, Maple Grove, Minnesota 55311-1566, a Minnesota corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

No related appeals or interferences are pending.

(iii) Status of Claims

Claims 1-27, 36 and 37 are pending in the application, stand rejected and are the subject of this appeal.

(iv) Status of Amendments

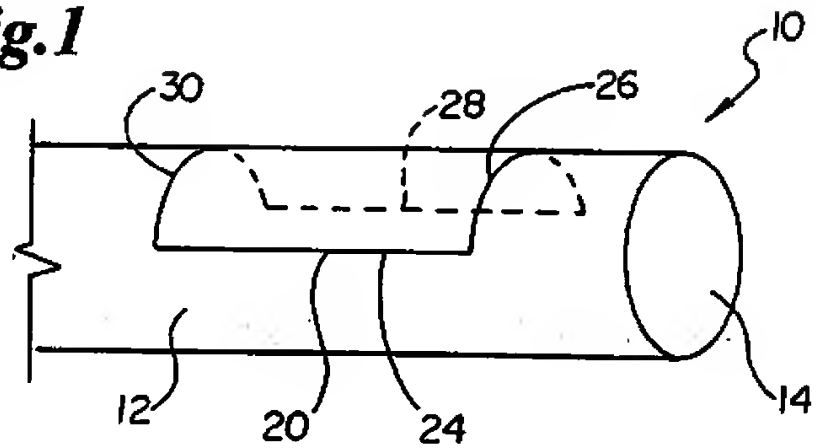
An Amendment After Final was filed on November 14, 2008, which presented arguments and amended claim 22 to change its dependency. The Amendment After Final was entered, as indicated in the Advisory Action mailed December 11, 2008.

A second Amendment After Final was filed with the Notice of Appeal on December 18, 2008. Claims 21 and 23 were amended to change their dependencies. The second Amendment After Final was entered, as indicated in the Advisory Action mailed January 15, 2009.

(v) Summary of Claimed Subject Matter

Independent claim 1 recites a medical device 10 and a marker wire 20 permanently coupled to the medical device. See Figure 1, provided below, and page 6, lines 1-5. The medical device 10 has a length and a longitudinal axis. The marker wire 20 extends such that a first portion 26 of the marker wire extends in a circumferential direction about the longitudinal axis of the medical device and a second portion 24 of the marker wire extends in a direction parallel to the longitudinal axis of the medical device. See page 8, lines 2-4. At least a portion of the marker wire defines the perimeter of a closed area, the closed area having a length that is less than the length of the medical device. See page 8, lines 23-26. The rotational orientation of the marker wire 20 may be determined using an imaging device when the medical device is positioned within a bodily lumen. See page 2, lines 21-22.

Fig.1



Claim 8 depends from claim 1 and requires the medical device 10 to comprise a device that may be implanted within a bodily lumen. See Figure 2 and page 8, lines 27-29.

Clam 9 depends from claim 1 and requires the medical device 10 to comprise a stent. See Figure 2 and page 8, lines 27-29.

Claim 10 depends from claim 9 and requires the stent to be self expanding. See page 10, lines 16-17.

Claim 11 depends from claim 9 and requires the stent to comprise a graft 42 that covers a portion of the stent, wherein the graft 42 is aligned with the closed area defined by the marker wire 20. See Figure 4, provided below, and page 10, lines 15-16 and 21-24.

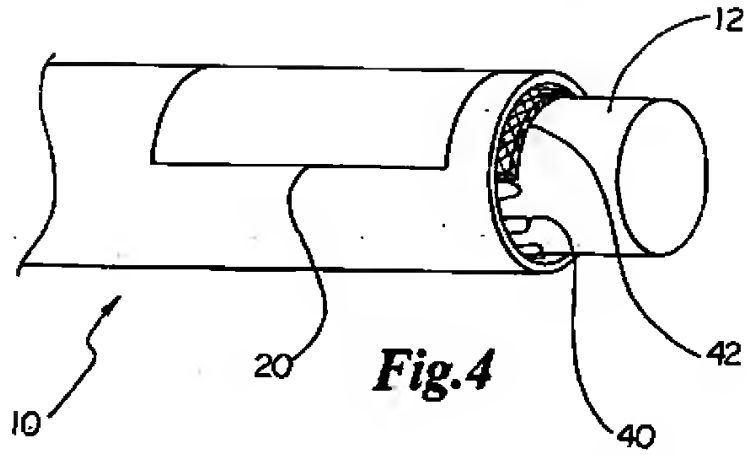


Fig.4

Claim 12 depends from claim 1 and requires the medical device to comprise an expansion balloon. See Figure 19 and page 15, lines 17-20.

Claim 13 depends from claim 1 and requires the marker wire 20 to comprise an MRI marker. See page 6, lines 8-9 and 15-18.

Claim 14 depends from claim 11 and requires the graft 46 to define an arc length, and the first portion 26 of the marker wire 20 to define a similar arc length. See Figure 2 and page 9, lines 11-12.

Claim 26 depends from claim 24, which depends from claim 1. Claim 26 requires the apparatus of claim 1 to comprise a lumen 52 and a port 68, and that the marker wire 20 extends about a rim of the port 68. See Figure 20, provided below, and page 16, lines 1-24.

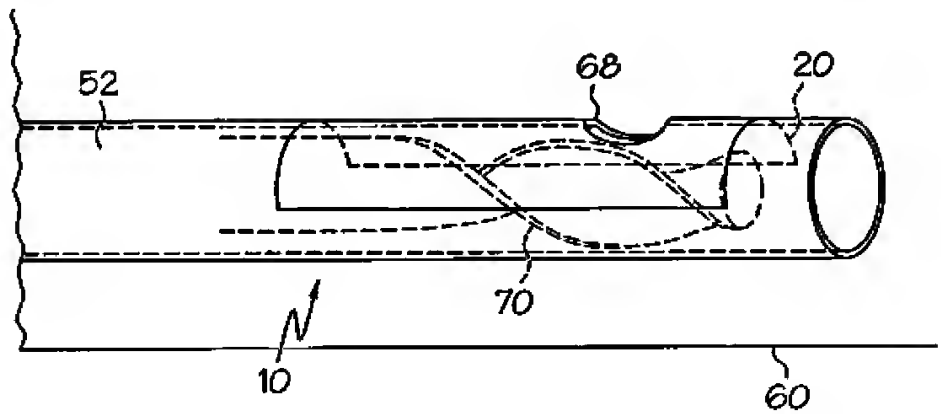


FIG. 20

Independent claim 15 recites a medical device 10 and a marker wire 20 coupled to the medical device. The marker wire extends such that a first portion 26 of the marker wire extends in a circumferential direction about the longitudinal axis of the medical device and a second portion 24 of the marker wire extends in a direction parallel to the longitudinal axis of the medical device. See page 8, lines 2-4. The rotational orientation of the marker wire may be determined using an imaging device when the medical device is positioned within a bodily lumen. See page 2, lines 21-22. The marker wire 20 further comprises a first directional indicator 36 oriented in a direction non-parallel to the longitudinal axis. See Figure 9 and page 12, lines 2-5.

Claim 17 depends from claim 16, which depends from claim 15. Claim 17 requires the directional indicator 36 to form a symbol when viewed at a proper rotational orientation using an imaging device. The symbol is an arrow. See Figures 9 and 10, and page 12, lines 9-14.

Fig.9

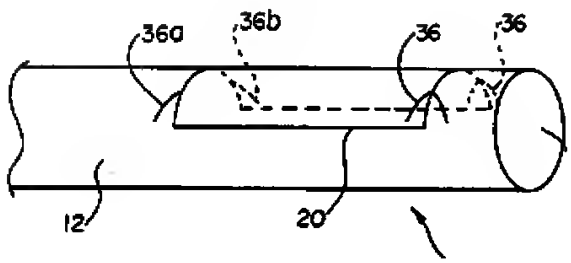
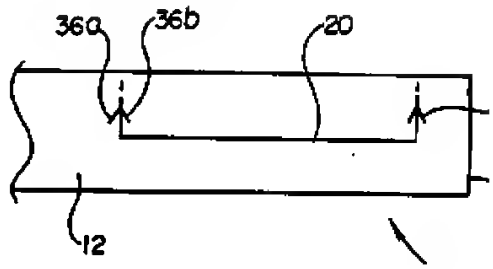


Fig.10



Claim 20 depends from claim 19, which depends from claim 15. Claim 19 recites a second directional indicator 36b that is offset from the first directional indicator 36a in a circumferential direction. The first directional indicator 36a and the second directional indicator 36b combine to form a symbol when viewed at a proper rotational orientation using an imaging device. See Figures 9 and 10, and page 12, lines 15-23.

Claim 21 depends from claim 20 and requires the symbol to be an arrow. See Figure 10 and page 12, lines 9-14.

Claim 22 depends from claim 20 and further recites a partial graft 42, wherein the symbol indicates the orientation of the partial graft. See page 12, lines 11-14.

Claim 23 depends from claim 20 and requires the symbol to be viewable over a rotational range of 5° or less. See page 12, lines 19-23.

Independent claim 36 recites a medical device 10 having a length and a longitudinal axis and a marker wire 20 permanently coupled to the medical device. See page 6, lines 1-5. The marker wire has a first end and a second end. The first end and the second end are offset from one another along the length of the device. The first end and the second end are offset from one another in a circumferential direction about the longitudinal axis of the device. See page 2, line 30-page 3, line 2. The rotational orientation of the marker wire may be determined using an imaging device when the medical device is positioned within a bodily lumen. See page 2, lines 21-22.

Independent claim 37 recites a method of positioning an implantable medical device within a bodily lumen comprising: a) providing a medical device having a rotational marker, the rotational marker comprising a wire loop; b) inserting the medical device into a bodily lumen and maneuvering the device to a worksite; c) viewing the worksite and the device through an imaging device, the rotational marker being visible upon the imaging device, wherein the rotational orientation of the wire loop may be determined using the imaging device; and d) positioning the medical device to a proper rotational orientation using the rotational marker as viewed upon the imaging system. See Figure 1 and page 3, lines 8-17.

(vi) Grounds of Rejection to be Reviewed on Appeal

Issue 1: Whether the Examiner erred in rejecting claims 1-10, 12, 15-21, 23-27, 36 and 37 under 35 USC § 103 over Lee (US 5203777) in view of Kittrell (US 4718417).

Issue 2: Whether the Examiner erred in rejecting claim 13 under 35 USC § 103 over Lee in view of Kittrell and further in view of Pacetti (US 6574497).

Issue 3: Whether the Examiner erred in rejecting claims 11, 14 and 22 under 35 USC § 103 over Lee in view of Kittrell and further in view of Armstrong (US 2002/0099431).

(vii) Argument

Issue 1: Whether the Examiner erred in rejecting claims 1-10, 12, 15-21, 23-27, 36 and 37 under 35 USC § 103 over Lee (US 5203777) in view of Kittrell (US 4718417)

The rejections asserted by the Examiner under 35 USC § 103 are traversed because the applied references do not disclose or suggest the device or method recited in the rejected claims. The rejections propose a modification to Lee in an attempt to reach the pending claims; however, the proposed modification stems from a hindsight motivation that goes beyond the actual teachings of the applied references. The rejections impermissibly use Applicant's disclosure to reconstruct the teachings of Lee, reading in teachings gleaned from Applicant's disclosure and asserting an overly broad interpretation of Lee. The Examiner relies on the impermissibly broadened characterization of the prior art in making the rejections. A person having ordinary skill in the art, viewing the applied references without knowledge of Applicant's invention, would not have been led to a device described by the pending claims.

Independent Claim 1

Independent claim 1 recites a "marker wire extending such that a first portion of the marker wire extends in a circumferential direction about the longitudinal axis of the medical device and a second portion of the marker wire extends in a direction parallel to the longitudinal axis of the medical device, at least a portion of the marker wire defining the perimeter of a closed area."

The applied references do not disclose or suggest a marker wire in accordance with claim 1.

Lee teaches a marking system having a first marker 60 and a second marker 62, wherein the markers 60, 62 are preferably rectangular in shape and made of metal foil. See Figure 2, provided below, and column 5, lines 5-14.

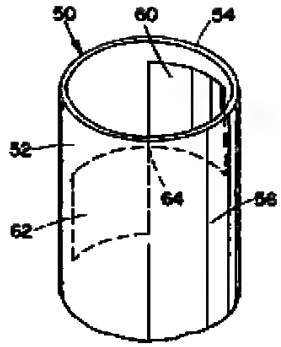


FIG. 2

The Examiner proposes to replace the solid foil markers of Lee with a wire outline of their perimeter (see Final Office Action at page 5); however, neither Lee nor Kittrell includes any teaching that would motivate a person of skill in the art to make such a replacement. Although the Examiner asserts that Lee describes the radiopaque markers in an open-ended way, the only type of radiopaque marker that Lee actually teaches is a solid foil/filled polygonal shape. Lee does not disclose or suggest a marker that comprises a wire outline.

Kittrell similarly does not disclose or suggest a rotational wire marker in accordance with claim 1. Although the rejection cites to Kittrell in an attempt to show a teaching of a wire marker (see Final Office Action at page 5), there is no correlation between the Kittrell wire embodiment and any shape outline. Kittrell's teaching of a "wire marker" is limited to a teaching of multiple windings of wire 13g that collectively form a band of material, which is an alternative embodiment for the solid band 13h illustrated in Figure 7D. See e.g. column 9, lines 35-39 and Figures 7C and 7D, provided below.

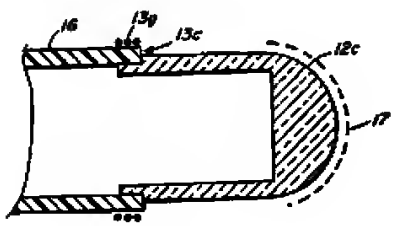


FIG. 7C

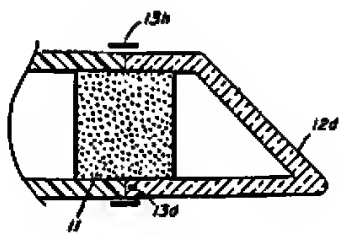


FIG. 7D

Kittrell teaches that these markers 13g, 13h "serve both as a radio-opaque marker and provide mechanical support to the optical shield 12." See column 9, lines 35-39. Thus, the Kittrell wire windings 13g of Figure 7c are collectively equivalent to the solid band marker 13h of Figure 7D. Both embodiments provide radiopacity and mechanical structure, and are specific to

the optical shield/laser catheter device taught by Kittrell. Neither embodiment provides any motivation to modify the foil areas of Lee by substituting an outline perimeter, as proposed by the Examiner.

"Obviousness requires a suggestion of all limitations in a claim." CFMT, Inc. v. Yieldup Intern. Corp., 349 F.3d 1333, 1342 (Fed. Cir. 2003).

Neither Lee nor Kittrell discloses or suggests a wire marker "extending such that a first portion of the marker wire extends in a circumferential direction about the longitudinal axis of the medical device and a second portion of the marker wire extends in a direction parallel to the longitudinal axis of the medical device," as recited in claim 1. Thus, rejection has not shown a prior art teaching of each limitation recited in independent claim 1, and claim 1 is patentable over Lee in view of Kittrell under 35 USC § 103.

Further, Kittrell's mere disclosure of a wound-wire marker band at the end of a catheter provides absolutely no motivation to redesign the Lee foil markers as proposed in the rejection. Lee teaches that a solid area of material provides visibility under fluoroscopy. There is no teaching in Lee or Kittrell that would provide a common sense rational to a person of skill in the art to replace Lee's foil areas with a wire outline shaped according to the boundary of the foil areas, as proposed in the Examiner's rejection.

When determining obviousness using a combination of references, the prior art must be considered as a whole, without the benefit of the impermissible hindsight vision afforded by the claimed invention. The prior art must be applied in the context of their significance to a technician at the time the invention was made, without knowledge of the applicant's invention. Taking into account the evidence of common knowledge and the common sense of the skilled person, there must be some evidence of a suggestion, teaching or motivation that would have led the skilled person to produce the invention as claimed. *In re Translogic Technology Inc.*, 84 USPQ2D 1929, 1937 (Fed. Cir. 2007); *Ortho-Mcneil Pharmaceutical Inc. v. Mylan Laboratories Inc.* 86 USPQ2D 1196, 1201-1202 (Fed. Cir. 2008).

The Supreme Court in *KSR International Co. v. Teleflex Inc.,* 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) states: "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'"

It is impermissible to simply engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template, picking and choosing among isolated disclosures in the various documents to supply elements to fill the gaps. The MPEP discusses the legal concept of *prima facie* obviousness and articulates how the obviousness determination is to be made:

> To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

MPEP § 2142 (emphasis added).

The Examiner asserts that Lee teaches an equivalence between filled shapes and outlines – "The examiner turns to fig. 4 of Lee to show that a hollow rectangle provides the same function as the filled rectangle....Fig 4 shows that either a filled rectangle or just a boundary of one can be used in Lee, as either fulfills the function (functional equivalents)." See Final Office Action at page 2. This assertion is traversed, as it can only be reached by impermissibly reading Applicant's teachings of an outline marker into the Lee disclosure.

Lee cannot teach equivalence between solid shapes and wire outlines because it does not disclose or suggest wire outlines. The assertion of equivalence impermissibly expands the scope of Lee using Applicant's teachings as a roadmap. Although Lee and the present claims both relate to radiopaque markers (e.g. a common genus), Lee teaches a different, specific type (e.g. species) of marker than is recited in the present claims. Lee only teaches foil/solid areas being used for rotational orientation, and does not disclose or suggest a wire outline. The only teaching of using a wire outline to determine rotational orientation appears in Applicant's disclosure, and the rejection impermissibly reads this teaching into the Lee disclosure. Thus, the rejection impermissibly characterizes Lee as teaching both solid and outline species, when in

reality, Lee only teaches the foil/solid species. The characterization of Lee asserted in the rejection fails to step away from Applicant's invention to look objectively at the teachings of Lee for what they would have taught a skilled person at the time of the invention.

In other words, a disclosure of Species A in a reference cannot establish that Species A and Species B are functionally equivalent, when the reference does not disclose or suggest Species B. In the present application, Lee cannot establish that solids and outlines are equivalent, when Lee only discusses solids, and the only discussion of outlines is contained in Applicant's teachings.

At first glance, the solid foil areas illustrated in Figure 4 may appear similar to a depiction of a wire outline; however, the appearance is merely an artifact of the black and white line drawings required in a patent, and Lee does not include any teaching of a wire outline. Figure 4 is not an accurate representation of how the Lee device would appear under fluoroscopy. The Examiner has asserted, "when interpreting a solid region in an image it is the edge, or outline, of the solid region that defines the marker, such as is shown in fig 4 where only the outlines of the square markers are shown." See Advisory Action. This assertion is traversed. A person of ordinary skill in the art would recognize that when viewed under fluoroscopy, the Lee markers would appear as solid glowing areas with no distinct edge. A person of ordinary skill in the art would not interpret Figure 4 as teaching anything about wire outline markers because Lee does not disclose or suggest wire outline markers. The Examiner's assertion stems from an impermissible hindsight use of Applicant's teachings being read into the Lee disclosure.

The Examiner makes a similar assertion with respect to Figure 7A of Lee, which shows a foil marker having an E-shape.

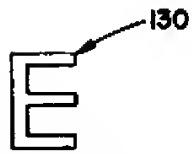


FIG. 7A

The Examiner asserts that Lee teaches an outline of the letter E. See Advisory Action. This assertion is traversed. Lee actually teaches a foil E-shape, and Figure 7A does not teach an outline marker formed according to the boundary of the E-shape.

The Examiner has not presented a clear reason why a person of ordinary skill in

the art, when viewing the applied references without hindsight, would have been motivated to replace the solid/foil shapes taught by Lee with wire outlines as taught by Applicant. Therefore, a *prima facie* case of unpatentability has not been presented under 35 USC § 103 against claim 1, or any claims dependent therefrom. Accordingly, Applicant requests that the Board reverse the Examiner's rejection of claims 1-10, 12 and 23-27 under 35 USC § 103 over Lee in view of Kittrell.

Dependent Claim 8

Claim 8 depends from claim 1 and recites, "wherein the medical device comprises a device that may be implanted within a bodily lumen." Neither Lee nor Kittrell specifically teaches a device suitable to be implanted within a bodily lumen. Lee discusses a catheter, angioscope and atherectomy device. See column 1, lines 11-19. Kittrell discusses an optical catheter. A person of ordinary skill would recognize that the applied references teach devices that are temporarily placed in a bodily lumen and removed – they are never implanted within the lumen, as required by claim 8.

Therefore, Lee and Kittrell do not disclose or suggest a device in accordance with claim 8, and even if the modification proposed by the Examiner were performed, the resulting device would not meet the limitations of claim 8. Applicant requests that the Board separately reverse the Examiner's rejection of claim 8.

Dependent Claim 9

Claim 9 depends from claim 1 and recites, "wherein the medical device comprises a stent." Neither Lee nor Kittrell discloses or suggests a stent. Further, the Examiner's proposed modification would result in wire outlines shaped according to the markers of Lee Figure 4 being placed directly on the stent. A person of ordinary skill in the art would recognize that such markers would likely interfere with the stent's ability to expand. Either the stent would not be able to properly expand, or expansion of the stent would skew and deform the wire outlines such that they would no longer be capable of conveying the rotation orientation of the stent.

Therefore, Lee and Kittrell do not disclose or suggest a device in accordance with claim 9, and there would not be a reasonable expectation of success associated with the

modifications to Lee and Kittrell necessary to arrive at a device that meets the limitations of claim 9. Applicant requests that the Board separately reverse the Examiner's rejection of claim 9.

Dependent Claim 10

Claim 10 depends from claim 9, discussed above. Claim 10 requires the stent to be self-expanding. Neither Lee nor Kittrell discloses or suggests a self-expanding stent. Applicant requests that the Board separately reverse the Examiner's rejection of claim 10.

Dependent Claim 12

Claim 12 depends from claim 1 and recites, "wherein the medical device comprises an expansion balloon." The Examiner asserts that Lee teaches tubular devices that would include expansion balloons (see Final Office Action at page 4); however, Lee does not disclose or suggest a balloon. The rejection does not explain how the modified Lee markers that would be used with an expansion balloon. A person of ordinary skill in the art would recognize that as a balloon transitions from an uninflated state to an inflated state, the Lee markers would likely interfere with proper expansion. The expansion would likely skew and deform the Lee markers such that they would no longer be capable of conveying the rotation orientation of the balloon. The Examiner has not provided a clear reason why a person of ordinary skill in the art, when viewing the applied references without hindsight, would have been motivated to modify Lee as necessary to reach claim 12. Applicant requests that the Board separately reverse the Examiner's rejection of claim 12.

Dependent Claim 26

Claim 26 depends indirectly from claim 1, and requires the claimed medical device to comprise a lumen and a port. Further, the marker wire "extends about a rim of the port."

Lee teaches a medical device having a port, but does not disclose or suggest any marker wire extending about the port as required by claim 26. See Figure 9, provided below.

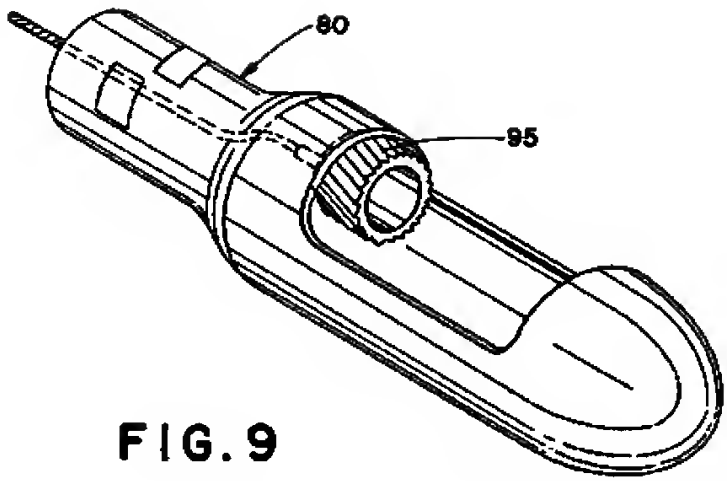


FIG. 9

Lee Figure 9 shows Lee's foil area markers offset from the port. The applied prior art does not include any teaching that would motivate a person of skill in the art to replace the Lee markers of Figure 9 with a wire that extends about the port, and the rejection does not discuss any reason for doing so. Further, the Examiner does not discuss the limitations of claim 26 in the Final Office Action. Therefore, Applicant asserts that the Examiner has not presented a *prima facie* case of obviousness against claim 26 and requests that the Board separately reverse the rejection of claim 26.

Independent Claim 15

Independent claim 15 recites a "marker wire extending such that a first portion of the marker wire extends in a circumferential direction about the longitudinal axis of the medical device and a second portion of the marker wire extends in a direction parallel to the longitudinal axis of the medical device." These limitations are similar to limitations included in independent claim 1, discussed above. Applicant reasserts arguments from the above section – namely that neither Lee nor Kittrell disclose or suggest a marker wire that meets the recited limitations, and that the Examiner has used improper hindsight in proposing modifications that would result in such a marker wire.

Claim 15 also recites "the marker wire further comprises a first directional indicator oriented in a direction non-parallel to the longitudinal axis." To satisfy these limitations, the Examiner relies upon an embodiment of the Lee foil marker formed in an E-shape. See e.g.

Lee Figure 7A and the Final Office Action at pages 5-6.

The Examiner cites to Kittrell in an attempt to teach a wire marker and find motivation to replace the Lee markers with wire; however, Kittrell's mere disclosure of a wound-wire marker band as a volumetric equivalent to a solid ring marker band does not provide any motivation to redesign the Lee foil markers and substitute a wire perimeter of an E-shape for the foil E-shape. The rejection relies upon an impermissible hindsight use of Applicant's disclosure in an attempt to reach the pending claims. Although the Examiner states that it would have been possible to modify Lee as proposed in the rejection, the Examiner does not provide a clear reason why a person of ordinary skill in the art would have been motivated to make such a modification. Therefore, the Examiner has not presented a *prima facie* case of obviousness against claim 15, or any claim dependent therefrom. Applicant requests that the Board reverse the Examiner's rejection of claims 15-21 and 23 under 35 USC § 103 over Lee in view of Kittrell.

Dependent Claim 17

Claim 17 depends indirectly from claim 15 and requires a directional indicator to form a symbol when viewed at a proper rotational orientation using an imaging device, "wherein the symbol is an arrow."

The Examiner has not shown a prior art teaching of a radiopaque marker forming an arrow symbol. The rejection merely provides a conclusory statement that using a symbol would have been obvious. See e.g. Final Office Action at page 6.

The rejection has not provided any clear reason why a person of ordinary skill in the art would have been motivated to modify Lee in a way that would form an arrow symbol in the radiopaque marker. Therefore, the Examiner has not provided a *prima facie* case of obviousness against claim 17. Applicant requests that the Board separately reverse the Examiner's rejection of claim 17.

Dependent Claim 20

Claim 20 depends indirectly from claim 15 and requires first and second directional indicators that are offset from one another in a circumferential direction, "wherein the first directional indicator and the second directional indicator combine to form a symbol when viewed

at a proper rotational orientation using an imaging device."

An example of a device according to claim 20 is shown in Figures 9 and 10, provided below. The first directional indicator 36a and second directional indicator 36b will combine to form an arrow, as shown in Figure 10, when viewed at a proper rotational orientation.

Fig.9

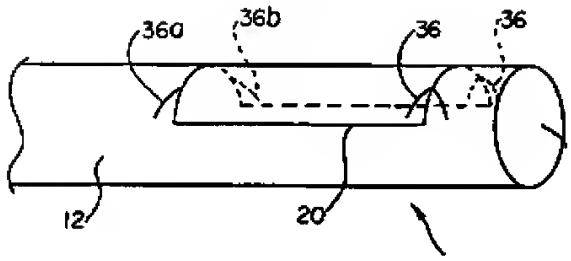
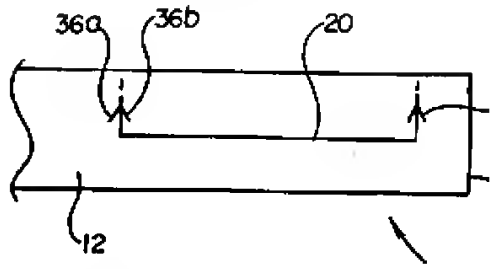


Fig.10



Neither Lee nor Kittrell discloses or suggests a marker in accordance with claim 20. The rejection does not discuss the specific first and second directional indicator limitations of claim 20. The rejection only discusses the E-shape, which does not satisfy the limitations of claim 20. See e.g. Final Office Action at pages 5-6. Therefore, a *prima facie* case of obviousness has not been presented against claim 20, and Applicant requests that the Board separately reverse the Examiner's rejection of claim 20.

Dependent Claim 21

Claim 21 depends from claim 20 and requires the symbol formed by the first and second directional indicators to be an arrow. The applied references do not disclose or suggest these limitations, and the rejection does not discuss first and second directional indicators forming an arrow. Therefore, a *prima facie* case of obviousness has not been presented against claim 21, and Applicant requests that the Board separately reverse the Examiner's rejection of claim 21.

Dependent Claim 23

Claim 23 depends from claim 20 and requires the symbol formed by the first and second directional indicators to be "viewable over a rotational range of 5° or less."

The rejection does not discuss these limitations. In fact, the Examiner asserts that "in fig. 4 as the catheter is being rotated 45 degrees from the 0 degree position the marker 60,

which in a different embodiment could be the E or an arrow symbol can is still viewable." See Office Action at page 6. Applicant interprets the Examiner's statement as asserting that the Lee symbol is viewable over a rotational range of at least 45 degrees, which is clearly outside the scope of claim 23. The rejection has not proposed any device that would meet the limitations of claim 23. Therefore, a *prima facie* case of obviousness has not been presented against claim 23, and Applicant requests that the Board separately reverse the Examiner's rejection of claim 23.

Independent Claim 36

Independent Claim 36 recites a "marker wire having a first end and a second end, the first end and the second end being offset from one another along the length of the device, the first end and the second end being offset from one another in a circumferential direction about the longitudinal axis of the device." The rejection does not discuss these limitations.

The Examiner proposes to replace each foil rectangle of Lee with a wire outline shaped according to the perimeter of the foil rectangle. See Final Office Action at page 5. If a wire were shaped into such a rectangle or closed loop, the first end and second end of the wire would contact one another and be located in essentially the same position. The wire would not have first and second ends offset circumferentially and longitudinally as required by claim 36. Therefore, Lee and Kittrell do not disclose or suggest each limitation of claim 36, and even if the modification proposed by the Examiner were performed, the resulting device would not meet the limitations of claim 36. Applicant requests that the Board reverse the Examiner's rejection of independent claim 36.

Independent Claim 37

Independent claim 37 recites a method comprising "providing a medical device having a rotational marker, the rotational marker comprising a wire loop."

The applied references do not disclose or suggest a rotational marker that comprises a wire loop. As discussed above with respect to independent claim 1, the Examiner has used impermissible hindsight in proposing the modification to Lee. Lee does not disclose or suggest any wire markers. Kittrell teaches a wound-wire marker as discussed above; however, the Kittrell marker does not provide any indication of rotational orientation of the medical device,

and the combination of Lee and Kittrell does not provide any motivation to replace the foil areas of the Lee markers with a wire outline as proposed by the Examiner. The rejection does not provide an actual reason why a person of skill in the art would have been motivated to modify Lee as proposed. Therefore, a *prima facie* case of obviousness has not been presented against independent claim 37, and Applicant requests that the Board reverse the Examiner's rejection of claim 37.

Issue 2: Whether the Examiner erred in rejecting claim 13 under 35 USC § 103 over Lee in view of Kittrell and further in view of Pacetti (US 6574497)

Claim 13 depends from claim 1, which recites a "marker wire extending such that a first portion of the marker wire extends in a circumferential direction about the longitudinal axis of the medical device and a second portion of the marker wire extends in a direction parallel to the longitudinal axis of the medical device, at least a portion of the marker wire defining the perimeter of a closed area." These limitations are discussed above under Issue 1. Applicant's assertions against the rejection of claim 1 are applicable against the rejection of claim 13.

Claim 13 further requires the marker wire to be an MRI marker. The rejection merely cites to Pacetti, which discusses MRI markers, and makes a conclusory statement that use of MRI markers would have been obvious. See Final Office Action at page 6.

The Examiner's conclusory statement does not amount to a proper assertion of *prima facie* obviousness against claim 13. The rejection does not explain how the Lee device would have been modified in order to achieve an MRI marker. Thus, the rejection does not apply the teachings of Pacetti within the context of the Lee device.

Lee teaches markers that comprise a solid foil area. See e.g. Figure 2 and column 5, lines 5-14. In order to arrive at a device that meets the limitations of claim 13, the Lee solid foil markers must be replaced with a wire perimeter, for example as proposed by the Examiner in the rejection of claim 1. With respect to this modification, Applicant has asserted that the Examiner used impermissible hindsight to read Applicant's teachings into the Lee disclosure. In order to arrive at an MRI marker, the device must be further modified such that the marker would be visible under MRI.

Within the context of the Lee device, the rejection does not explain why a person of ordinary skill in the art who desired to make the Lee device visible under MRI would have been motivated to replace the foil area markers with the wire perimeter, as proposed by the Examiner in order to reject claim 1. For example, if a person of ordinary skill in the art considered replacing the gold foil markers of Lee with a paramagnetic material visible under MRI, the rejection does not explain any motivation for substituting a wire perimeter for Lee's foil area.

The addition of Pacetti to the combination of Lee and Kittrell does not remedy the shortcomings of Lee and Kittrell discussed above under Issue 1. Pacetti does not provide any motivation to modify Lee or Kittrell in a way that would arrive at a modified device meeting the limitations of claim 13, and the Examiner has not properly explained how Lee would be modified in order to reach claim 13. Therefore, a *prima facie* case of obviousness has not been presented against claim 13, and Applicant requests that the Board reverse the Examiner's rejection of claim 13.

Issue 3: Whether the Examiner erred in rejecting claims 11, 14 and 22 under 35 USC § 103 over Lee in view of Kittrell and further in view of Armstrong (US 2002/0099431)

Claims 11 and 14 depend from claim 1, which recites a "marker wire extending such that a first portion of the marker wire extends in a circumferential direction about the longitudinal axis of the medical device and a second portion of the marker wire extends in a direction parallel to the longitudinal axis of the medical device, at least a portion of the marker wire defining the perimeter of a closed area." These limitations are discussed above under Issue 1. Applicant's assertions against the rejection of claim 1 are applicable against the rejection of claims 11 and 14.

Claim 11 depends from claim 9, which Applicant argues separately above under Issue 1 - namely that the combination proposed in the rejection of claim 9 would not present a reasonable expectation of success. Applicant's assertions against the rejection of claim 9 are applicable against the rejection of claim 11.

Claim 11 recites, "wherein the stent further comprises a graft that covers a portion

of the stent, wherein the graft is aligned with the closed area defined by the marker wire."

The rejection of claim 11 asserts that Armstrong teaches a stent-graft aligned with a radiopaque marker, and asserts that the subject matter of claim 11 would have been obvious. See Final Office Action at page 7.

In rejecting claim 11, the Examiner has again used impermissible hindsight in reading limitations into the prior art. The applied references do not disclose or suggest a marker wire defining a perimeter of a closed area, and a stent having a graft that covers a portion of the stent, wherein the graft is aligned with the closed area defined by the marker wire, as required by claim 11.

Armstrong, for example, merely states that a stent-graft can be aligned with radiopaque markers on a balloon catheter shaft. See paragraph 0104. Armstrong does not further describe the radiopaque markers on the balloon catheter shaft or discuss any specifics of the alignment. Armstrong does not provide any teaching of using a rotational marker to indicate the orientation of a partial graft.

Within the context of the Lee device, the rejection does not explain why a person of ordinary skill in the art who desired to combine the Lee device with an Armstrong stent-graft would have been motivated to replace Lee's foil area markers with the wire perimeter, as proposed by the Examiner in order to reject claim 1. For example, if a person of ordinary skill in the art considered using the solid foil markers of Lee with a graft, the rejection does not explain any motivation for substituting a wire perimeter for Lee's foil area.

The addition of Armstrong to the combination of Lee and Kittrell does not remedy the shortcomings of Lee and Kittrell discussed above under Issue 1. Armstrong does not provide any motivation to modify Lee or Kittrell in a way that would arrive at a modified device meeting the limitations of claim 11. Therefore, a *prima facie* case of obviousness has not been presented against claim 11, and Applicant requests that the Board reverse the Examiner's rejection of claim 11.

Claim 14 depends from claim 11 and requires the "first portion of the marker wire" recited in claim 1 to define an arc length that is similar to an arc length of the graft recited in claim 11. The Examiner does not specifically address the limitations of claim 14 and has not proposed a modification to the prior art that would meet these limitations. Further, the Lee device includes

multiple rectangular foil areas. Even if the foil areas were replaced with wire outlines as proposed by the Examiner, and the wire outlines were collectively placed to indicate the bounds of a partial graft, no wire outline would define an arc length similar to an arc length of the graft because the individual wire outlines are each smaller than the graft. Therefore, a *prima facie* case of obviousness has not been presented against claim 14, and Applicant requests that the Board reverse the Examiner's rejection of claim 14.

Claim 22 depends indirectly from independent claim 15, which is discussed above under Issue 1. Applicant's assertions against the rejection of claim 15 are applicable against the rejection of claim 22. Claim 22 also depends from claim 20, a dependent claim that is separately argued above under Issue 1. Applicant's assertions against the rejection of claim 20 are applicable against the rejection of claim 22.

Further, claim 22 recites a partial graft and requires the "symbol" recited in claim 20 to indicate the orientation of the partial graft. The Examiner has characterized the embodiment of Lee's E-shaped marker as including the claimed "symbol;" however, the Examiner has not explained how the E-shaped marker would be oriented with respect to the partial graft. Within the context of the Lee device, the rejection does not explain why a person of ordinary skill in the art who desired to combine the Lee device with an Armstrong stent-graft would have been motivated to replace the E-shaped foil area markers with the wire perimeter as previously proposed by the Examiner. The rejections have been made using impermissible hindsight, and the Examiner has not provided a reasonable explanation of an actual device that would have been formed as a result of modifying the Lee device according to teachings from Kittrell and Armstrong. Therefore, a *prima facie* case of obviousness has not been presented against claim 22, and Applicant requests that the Board reverse the Examiner's rejection of claim 22.

Argument Conclusion

Based on at least the foregoing arguments, Applicant respectfully submits that the rejections presented by the Examiner fail to establish a *prima facie* case of obviousness against any of the rejected claims. Accordingly, Applicant respectfully requests that the Board reverse all of the Examiner's rejections under 35 USC § 103.

Respectfully submitted,

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(viii) Claims Appendix

1. An apparatus comprising:

a medical device and a marker wire permanently coupled to said medical device, the medical device having a length and a longitudinal axis, the marker wire extending such that a first portion of the marker wire extends in a circumferential direction about the longitudinal axis of the medical device and a second portion of the marker wire extends in a direction parallel to the longitudinal axis of the medical device, at least a portion of the marker wire defining the perimeter of a closed area, the closed area having a length that is less than the length of the medical device, wherein the rotational orientation of the marker wire may be determined using an imaging device when the medical device is positioned within a bodily lumen.

2. The apparatus of claim 1, wherein the marker wire further comprises a third portion, the marker wire extending such that the third portion of the marker wire extends in a circumferential direction about the longitudinal axis of the medical device.

3. The apparatus of claim 2, wherein the marker wire further comprises a fourth portion, the marker wire extending such that the fourth portion of the marker wire extends in a direction along the longitudinal axis of the medical device.

4. The apparatus of claim 3, wherein the marker wire is continuous.

5. The apparatus of claim 3, wherein the marker wire comprises a closed circuit.

6. The apparatus of claim 1, wherein the medical device comprises a catheter.

7. The apparatus of claim 1, wherein the medical device comprises a catheter sheath.

8. The apparatus of claim 1, wherein the medical device comprises a device that may be implanted within a bodily lumen.

9. The apparatus of claim 1, wherein the medical device comprises a stent.

10. The apparatus of claim 9, wherein the stent is self expanding.

11. The apparatus of claim 9, wherein the stent further comprises a graft that covers a portion of the stent, wherein the graft is aligned with the closed area defined by the marker wire.

12. The apparatus of claim 1, wherein the medical device comprises an expansion balloon.

13. The apparatus of claim 1, wherein the marker wire comprises an MRI marker.

14. The apparatus of claim 11, wherein the graft defines an arc length, and the first portion of the marker wire defines a similar arc length.

15. An apparatus comprising:

a medical device and a marker wire coupled to said medical device, the medical device having a longitudinal axis, the marker wire extending such that a first portion of the marker wire extends in a circumferential direction about the longitudinal axis of the medical device and a second portion of the marker wire extends in a direction parallel to the longitudinal axis of the medical device, wherein the rotational orientation of the marker wire may be determined using an imaging device when the medical device is positioned within a bodily lumen;

wherein the marker wire further comprises a first directional indicator oriented in a direction non-parallel to the longitudinal axis.

16. The apparatus of claim 15, wherein the directional indicator forms a symbol when viewed at a proper rotational orientation using an imaging device.

17. The apparatus of claim 16, wherein the symbol is an arrow.

18. The apparatus of claim 16, wherein the symbol is viewable over a rotational range of 30° or less.

19. The apparatus of claim 15, further comprising a second directional indicator that is offset from the first directional indicator in a circumferential direction.

20. The apparatus of claim 19, wherein the first directional indicator and the second directional indicator combine to form a symbol when viewed at a proper rotational orientation using an imaging device.

21. The apparatus of claim 20, wherein the symbol is an arrow.

22. The apparatus of claim 20, further comprising a partial graft, wherein the symbol indicates the orientation of the partial graft.

23. The apparatus of claim 20, wherein the symbol is viewable over a rotational range of 5° or less.

24. The apparatus of claim 1, further comprising a lumen and a port.

25. The apparatus of claim 24, wherein the lumen is arranged to carry away bodily material.

26. The apparatus of claim 24, wherein said marker wire extends about a rim of the port.

27. The apparatus of claim 1, further comprising a rotational ablation device.

36. An apparatus comprising:

a medical device having a length and a longitudinal axis; and

a marker wire permanently coupled to said medical device;

the marker wire having a first end and a second end, the first end and the second end being offset from one another along the length of the device, the first end and the second end being offset from one another in a circumferential direction about the longitudinal axis of the device, wherein the rotational orientation of the marker wire may be determined using an imaging device when the medical device is positioned within a bodily lumen.

37. A method of positioning an implantable medical device within a bodily lumen comprising:

a) providing a medical device having a rotational marker, the rotational marker comprising a wire loop;

b) inserting the medical device into a bodily lumen and maneuvering the device to a worksite;

c) viewing the worksite and the device through an imaging device, the rotational marker being visible upon the imaging device, wherein the rotational orientation of the wire loop may be determined using the imaging device;

d) positioning the medical device to a proper rotational orientation using the rotational marker as viewed upon the imaging system.

(ix) Evidence Appendix

None

(x) Related Proceedings Appendix

None